

COLORADO STATE BOARD OF PHARMACY

January 21, 2010

Minutes

The Colorado State Board of Pharmacy meeting was convened by President Rich Doyle, R.Ph., at approximately 8:30 a.m. on Thursday, January 21, 2010 at 1560 Broadway, Conference Room 110D, Denver, CO 80202. Notice of this meeting was given in accordance with Division of Registrations Policy Number 80-17.

Board members attending were: Mary K. Arceneaux, R.Ph., Jeannine G. Dickerhofe, R.Ph., Rich Doyle, R.Ph., Katherine Edelblut, R.Ph., Paul Limberis, R.Ph., and Averil Strand, R.N.

Staff members attending were Wendy Anderson, R.Ph., Program Director; Chris Gassen, R.Ph., Chief Inspector; Tia Johnson, Complaint/Licensing Specialist; Susan Martin, R.Ph., Inspector; and Mark O'Neill, R.Ph., Inspector. Also present was Jo Kaye, Assistant Attorney General, to advise the Board.

APPROVAL OF MINUTES

The Board approved the minutes from the November 19, 2009 meeting as amended.

ADDITIONS TO THE AGENDA

None

APPEARANCES

Elizabeth Pace, CEO of Peer Assistance Services, discussed the proposed evaluation of the Pharmacy Peer Health Assistance Diversion Program. The evaluation will begin in the coming months. The results will be presented to the Board at a later meeting.

HEARINGS

The Board conducted a public hearing concerning additions to or amendments to regulations 4.00.00, 5.00.00, and 18.00.00 (3 CCR, 719-1). The hearing began at 9:30 a.m. and was held in Conference Room 110D at 1560 Broadway, Denver, Colorado 80202. The Board discussed the proposed changes to the rules then adopted regulations 4.00.00 and 18.00.00 as amended. The Board tabled action on the proposed changes to regulation 5.00.00.

REPORTS

President's Remarks

President Rich Doyle thanked Paul Limberis, RPH for serving as the Board's president for the past year. He thanked the Board for its hard work and congratulated them on the work accomplished.

Program Director's Report

Ms. Anderson presented the Board with a new policy by which Board staff would administratively conduct the continuing education audit and any issues with non-

compliance that came from such audit. The Board approved the new policy as amended. The Board then approved amendments to Policies 10-6, 20-3, 20-5, 30-7, and 40-1. In addition, the Board approved deleting policy 20-8, as it was no longer relevant.

The Board reviewed a memorandum from Board staff and approved the Division of Registrations reception area and the internet as being the appropriate venues to post public notices of the Board's meetings for 2010.

The Board then discussed the provision of eye prophylactic therapy by Direct-Entry Midwives. After due consideration, the Board instructed staff to discuss potential wording for statutory changes with the Office of Midwifery so as to allow prescription drug outlets to provide direct-entry midwives with the needed eye treatments.

Ms. Anderson provided the Board with an update on the dialog between the National Association of Boards of Pharmacy ("NABP") and the Pharmacy Compounding Accreditation Board ("PCAB"). To date, NABP has not made a decision as to whether or not it will "partner" with PCAB.

The Board then provided staff with topics for its February 2010 Planning Meeting.

Jeannine Dickerhofe, R.Ph. volunteered to be the Board of Pharmacy's observer for the Accreditation Council for Pharmacy Education's ("ACPE") evaluation of the Doctor of Pharmacy program at the Regis University School of Pharmacy. This review will occur on April 21-23, 2010.

Colorado Pharmacists Society (CPS) – Rich Doyle, RPh

The 18th Annual CPS Winter Continuing Education ("CE") Seminar was held on January 10-13, 2010 at the Riverfront Westin in Avon, Colorado. Fifteen hours of CE were provided. Over sixty pharmacists attended from all over the United States. Next year's Winter CE Seminar will be on January 9-12, 2011. It will be held at the same location.

Advances in Pharmacy Practice, a CE program providing 6 hours of ACPE approved continuing education, is being offered by CPS and the School of Pharmacy on February 20, 2010. The program will cover the topics of pain management, osteoporosis, alternative & complementary medicine, HIV/AIDS, new drugs, and pharmacy law.

Planning has already begun for the Annual Summer Meeting, June 17-19, 2010 in Estes Park where 10 hours of CE will be offered.

Governor's Expert Emergency Epidemic Response Committee (GEEERC) – Paul Limberis, RPh

None

Intern & School Relations – Jeannine Dickerhofe, RPh

Cathy Jarvis, Assistant Dean, University of Colorado Denver School of Pharmacy, reported that the school had a 98.1% pass rate on the NAPLEX and a 98% pass rate on the MPJE. She also reported that the number of applications for admission to the school are down.

Regis University School of Pharmacy reported that the students underwent their “White Coat Ceremony” on January 16, 2010. In addition, two more faculty members were hired.

Legislation - Jeannine Dickerhofe, RPh.

House Bill 1061 has been introduced which provides for the creation of a Medication Donation Program. This bill establishes a program that allows certain facilities to donate medications, medical devices and medical supplies to patients in Colorado that are uninsured and underinsured. The program is modeled after the “Colorado Cancer Drug Repository Act” of 2005.

Two more bills affecting pharmacy are anticipated. One will permit immunizations outside a pharmacy and the other will require the practitioner, who finds it to be in the best interest of a patient to not allow the substitution of an equivalent generic drug for the one actually prescribed, to indicate on the prescription the words “Brand Medically Necessary.”

The Department of Health Care Policy and Financing will be implementing a State Maximum Allowable Cost (“SMAC”) program as early as March 1. The program will initially include 140 generics. The Department will be surveying pharmacies in Colorado to determine the actual pharmacy acquisition cost. The SMAC will be pharmacy acquisition cost +18% and will be the fifth “lower of” methodology in pricing Medicaid prescriptions. An RFP is being prepared to find an entity that will administer this program at the anticipated cost of \$200,000-350,000 per year. The anticipated savings in 2010-2011 is approximately \$1 million. This would be added to the \$6.8 million savings as a result of the First Data Bank Lawsuit and \$5 million from changing the dispensing fee to AWP - 14.5% for brand and AWP-45% for generics.

Rules – Rich Doyle

None

Inspectors

The Board considered a report from Mr. Gassen regarding possible unregistered dispensing and distribution of prescription drugs by Praxair at several locations in Colorado. After due consideration, the Board voted to issue letters to each of the facilities detailing Colorado’s laws and explaining the types of registrations needed to distribute and dispense prescription drugs.

OLD BUSINESS

Complaints

Cases 2010-0972 & 2010-0973

Jeannine Dickerhofe, R.Ph. recused.

The Board noted and accepted the response from Kaiser Permanente Rock Creek Pharmacy. It determined no further action was necessary.

Aapex Community Pharmacy, Inc., OSP 5820

The Board reviewed a memorandum from Mr. Gassen regarding the dispensing practices of this pharmacy. After due consideration, it decided that no further action was necessary.

Stipulations

Calvin T. Tyree, Jr., RPH 16164

The Board reviewed an Agenda Memorandum from Ms. Johnson concerning Mr. Tyree's compliance with his Stipulation and Final Agency Order. After due consideration, the Board determined that no further action was necessary.

The Board did determine, however, that it would require individuals to obtain a rating of an "Unconditional Pass" on Professional/Problem Based Ethics ("ProBE") courses as a requirement of future stipulation and final agency orders.

Miscellaneous

Complaint Regarding Immunizations

Mary K. Arceneaux, R.Ph. recused.

The Board reviewed an Agenda Memorandum from Ms. Anderson concerning a complaint filed by Karen Scavetta, which had been previously reviewed by the Board at its November 19, 2009 and a more recent complaint filed by Ms. Scavetta, requesting that the Board reconsider its November 19th decision.

After consideration of the available information, the Board determined that its previous determination of a lack of jurisdiction concerning the matter should stand. The Board directed staff to inform Ms. Scavetta that the issue was essentially an employer-employee issue, and that a case will not be opened concerning the matter.

NEW BUSINESS

Complaints

Advanced Skin Solutions, Inc., unregistered

2009-4014

The Board voted unanimously to refer the case to executive session for discussion of possible disciplinary action.

After executive session, the Board voted to issue a Cease and Desist Order to Advanced Skin Solutions, for the unregistered dispensing of prescription drugs.

The Board also directed the initiation of a case, and the issuance of a Cease and Desist Order to Brian Barton for the unlicensed practice of pharmacy.

The Board also directed the issuance of Cease and Desist Orders to Wejeng Sheu, MD, Linhthi Phan, and Shu Chaun Sung Yang for the unregistered distribution of prescription drugs.

The Board also directed a referral of information to the Medical Board of California concerning Wejeng Sheu, MD, and a referral of information to the California State Board of Pharmacy concerning Dr. Sheu, Linhthi Phan, and Shu Chaun Sung Yang.

Caremark Florida Mail Pharmacy, OSP 5502 **2010-1453**

The Board voted unanimously to dismiss the case as being without merit.

Griss, Donald R., RPH 8481 **2010-1908**

Mary K. Arceneaux, R.Ph. recused.

The Board voted unanimously to refer the case to executive session for discussion of possible disciplinary action.

After executive session, the Board voted to refer the case for discipline.

Pak, June L., RPH 14407 **2010-1445**

Mary K. Arceneaux, R.Ph. recused.

The Board voted unanimously to refer the case to executive session for discussion of possible disciplinary action.

After executive session, the Board voted to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

Walgreens Long-Term Care Pharmacy # 11873 (SeniorMed Pharmacy) **PDO7-53**
2010-1358

The Board voted unanimously to refer the case to executive session for discussion of possible disciplinary action.

After executive session, the Board voted to dismiss the case as being without merit.

However, the Board directed letters of guidance to be sent to Walgreens Long-Term Care Pharmacy #11873 and to Walgreens Long-Term Care Pharmacy # 11917 reminding the pharmacies that when a pharmacist is not physically present in the pharmacy, the pharmacy must be enclosed and secured, and no non-pharmacist personnel shall remain in the pharmacy.

Snyder, Robert P., RPH 17402 **2010-1063**

The Board voted unanimously to dismiss case as being without merit.

Tassian, Pauline B., RPH 8381 **2009-4394**

Paul Limberis, R.Ph. recused.

The Board voted unanimously to refer the case to executive session for discussion of possible disciplinary action.

After executive session, the Board voted to refer the case for discipline.

Tyree, Calvin T., Jr., RPH 16164 **2010-1141**

The Board voted unanimously to refer the case to executive session for discussion of possible disciplinary action.

After executive session, the Board voted to issue a Letter of Admonition for violations of the Pharmaceuticals and Pharmacists Act.

Valentine, Dan M., RPH 12002

2010-0912

The Board voted unanimously to dismiss case as being without merit.

Walgreen Pharmacy #4596, PDO 24-77

2010-0978

The Board voted unanimously to refer the case to executive session for discussion of possible disciplinary action.

After executive session, the Board voted to refer the case for discipline.

The Board also directed the initiation of a case against Charles R. Lyon, RPH 15774.

Walgreen Pharmacy # 07252, PDO 44-20

2010-1732

The Board voted unanimously to refer the case to executive session for discussion of possible disciplinary action.

After executive session, the Board voted to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

Walgreen Pharmacy # 09212, PDO 575

2010-0913

The Board voted unanimously to refer the case to executive session for discussion of possible disciplinary action.

After executive session, the Board voted to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

LICENSING

Other Outlets, New

The Board approved the registration of no new other outlets.

Prescription Drug Outlets, New (In-State)

The Board approved the registrations of 6 new in-state prescription drug outlets.

Prescription Drug Outlets, New (Out-of-State)

The Board approved the registrations of 16 new nonresident prescription drug outlets.

Manufacturers, New

The Board approved the registrations of no new manufacturer.

Limited Licenses, New

The Board approved the registrations of no new limited licenses.

Wholesalers, New (In-State)

The Board approved the registrations of 1 new in-state Wholesalers.

Wholesalers, New (Out-of-State)

The Board approved the registrations of 20 new out-of-state Wholesalers.

Licensure by Examination and Score Transfer

The Board ratified the licensure of 14 applicants for licensure.

Licensure by License Transfer

The Board ratified the licensure of 20 applicants seeking licensure through license transfer. It was noted that these licensees met all of the requirements for licensing under the provisions of section 12-22-116, C.R.S.

LICENSURE ISSUES

Easy Scripts, Non-Resident Prescription Drug Outlet Applicant

After review of the available information, the Board voted to approve the application.

Pala-Tech Laboratories, Non-Resident Wholesaler Applicant

After review of the available information, the Board voted to table the application.

Patterson, Eugene S., Pharmacy Intern Applicant

After review of the available information, the Board voted to approve the application.

MISCELLANEOUS

Correspondence, etc.

Sandra Ihrig, e-mail dated 11/16/09

The Board determined that this matter would be better addressed with the Federal Drug Administration (FDA) and directed its staff to send a letter to Ms. Ihrig with this information.

Phenylbutazone in Horses – Veterinarians

The Board noted the information.

Policy Number 30-8 – Revised November 19, 2009

The Board noted the information.

Request from the Colorado State Division of Behavioral Health Regarding the Prescription Drug Monitoring Program.

The Board conditionally approved the request.

Steven J. Thorson, MD, correspondence dated 11/27/09

Mary K. Arceneaux, R.Ph. recused.

The Board voted unanimously to refer discussion to executive session for legal guidance.

After executive session, the Board directed correspondence sent to King Soopers, requesting a response to Dr. Thorson's concerns.

NABP – Update to NAPLEX Blueprint

The Board noted the information.

Prime Therapeutics, LLC, OSP 5588

The Board noted the information, and determined no further action was necessary.

EXECUTIVE SESSION

At 12:20 pm Board President Rich Doyle moved that that the Board enter into Executive Session to discuss with counsel disputes that are the subject of pending or imminent litigation, specific claims or grievances, or legal advice on specific legal questions, pursuant to CRS section 24-6-402 subsection (3)(a) roman (II), and matters required to be kept confidential by federal law or rules or state statutes pursuant to CRS sections 24-6-402 subsection (3)(a) roman (III) and 12-22-125.2 subsection (7)(a) including:

- Discussion with Counsel regarding the Rehabilitation Evaluation Committee report and other legal questions;
- Discussion with Counsel regarding the Case Status Report for matters that have been referred to the Expedited Settlement Program, including settlement negotiations, counteroffers and other legal questions;
- Discussion with Counsel regarding the legal basis for potential application denial, confidential letters of concern, disciplinary action, and, where warranted recommended settlement guidance regarding all matters referred to Executive Session earlier in the meeting;
- Discussion of the Legal Report.

Mr. Doyle further moved that the Board enter into Executive Session for the purpose of discussing reports of malpractice claim settlements required to be kept confidential by federal law or rules or state statutes pursuant to CRS 24-6-402 subsection (3)(a) roman (III), and CRS section 12-22-113.5 subsection 3, including case numbers: 2010-1450 and 2010-0901.

In addition, the Board President moved that the Board enter into Executive session for the purpose of discussing matters required to be kept confidential by federal law or rules or state statutes pursuant to CRS section 24-6-402 subsection (3)(a) roman (III) to include the Peer Assistance Services report of a voluntary participant.

Patient medical records are confidential pursuant to CRS section 25-1-1201 et seq. and CRS 13-90-107 subsection (1)(d). Drug and alcohol treatment records are also confidential pursuant to 42 Code of Federal Regulations Part 2, Article 21, Part 12, and CRS section 13-90-107.

The motion was seconded. The vote was unanimous with five votes approving the motion to go into Executive Session and none opposing.

The Board exited Executive Session at 3:25 pm.

Open Session

The Board voted to accept applicant PR10-176 into the Pharmacy Peer Health Assistance Diversion Program.

The Board voted to allow Pharmacy Peer Health Assistance Diversion Program participant PR-10-172 to return to the practice of pharmacy, once he has completed additional requirements as directed by the Rehabilitation Evaluation Committee.

Michelle Bloom, RPH 16464

The Board found that the public health, safety, or welfare imperatively required emergency action and voted to summarily suspend Ms. Bloom's pharmacist license should she fail to enter into an agreement with the Board within 10 business days, whereby she agrees not to practice pharmacy.

Case 2010-1450

The Board voted to dismiss the case as being without merit.

Case 2010-0901

The Board voted to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

ADJOURNMENT

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The Board adjourned at approximately 3:50 p.m.

Approved by Rich Doyle, R.Ph., President Date: February 18, 2010